

RESPONSE

In the action, the pending claims 1 - 14, 17-30 and 40-48 are rejected under 35 USC §102(b) and §103(a) over Muller et al, US 5,624,972, previously of record.

Examiner cites, as a basis for the §102(b) rejection, "In re Best", to the effect that "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." Similarly, in the §103 rejection, Examiner notes that since "There is no demonstration that greater than 30% propylene oxide will not work in the composition.", the product is obvious over Muller et al.

Applicant has made a Declaration under Rule 132, submitted herewith, which is believed to lay out an appropriate and sufficient factual background to distinguish Applicant's claims over the cited art.

§102(b) REJECTIONS

Claims 1-3 and 8 stand rejected under §102(b) over Muller. Claim 1 has been amended, and now again, as previously, contains the 7-% EO (i.e. 30% PO) limitation. Applicant believes that Examiner does not disagree that Muller et al prefer compositions having a high overall propylene oxide content, such as an overall ethylene oxide content of 2 - 30% (and the rest propylene oxide) at col 9 lines 1 - 9. In the examples, the isocyanate tipped polymers have PO contents of 72% in E and 89% in F and (probably) A.

However, broader ranges are mentioned for individual polymer components (as opposed to averages over the entire preparation), including 10 - 80% EO in random copolymers, vs. 2 - 30% in block copolymers and up to 50% EO in random/block copolymers (col. 5 lines 14 - 25). All of these compositions are intended to make a resilient, dry foam.

In Applicant's experience, there is a limited range of PO:EO ratios that are suitable for the particular use of formation of hydrogel-type tissue adhesives. This is the origin of the limitation of 10 - 30% in the claims. This limitation has been derived from experiment, as

opposed to any specific limitation in the art. In order to make the distinction clear, a Declaration under Rule 132 by the inventor is presented to confirm the existence and nature of the preferred ratio of monomers in compositions suitable for use as tissue adhesives.

The Muller et al reference demonstrates the manufacture of a resilient foam. The range of EO:PO in the working examples of Muller et al are each well above 50% PO, and no enablement of values below 50% PO is to be found. While general range statements can be found in Muller et al, they are not enabled in the range of PO below 50%. There is no evidence that he experimented in that region.

In contrast, as substantiated in the Declaration, Applicants have experimented in the region from below 10% to about 50% (by weight; 42% by number) of PO in the polymer. The 50% PO polymer is not suitable: it is not hydrophilic enough to disperse well in water, or to wet tissue, or to form a hydrogel with a high percentage of water. The 25% PO polymer described in the specification was commercially available; it was suitable. An upper limit of 30% was estimated. There is no evidence of a critical limit in PO values in Muller et al, and so the claims are novel over Muller.

Hence, the rejection under §102 of claims 1-3 and 8, as presently amended, is respectfully traversed, and passage of the claims to issue is respectfully requested.

§103 Rejections

Claims 4-7, 9-14, 17-30 and 40-48 are rejected under §103(a) over Muller et al. (Claim 1 has been re-amended to again contain the 70% EO limitation, and the claims may now all be covered by the §103(a) rejection.). The remaining issue with these claims appears to be that there is no demonstration for a difference in properties above 30%. Applicants believe that the Rule 132 Declaration provides a proper basis and substantiation for Applicant's discovery that there actually is a significant difference in tissue adherence above this level. The prior art does not find such a limitation; it has been discovered by experimentation by applicants, and therefore it is not obvious, as well as novel. Passage of these claims to issue is respectfully requested.

It is believed that no fee is due with this communication. If any fee is due, please charge it to my USPTO Deposit account, 50-3300.

Examiner is invited to contact the undersigned if there are any unresolved issues that can be resolved by conversation, correspondence or an interview.

Sincerely,

A handwritten signature in black ink, appearing to read "Francis H Kirkpatrick", with a stylized, cursive script.

Francis H Kirkpatrick

35,219

978-790-7186

fckirk@post.harvard.edu